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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,602	03/23/2001	Javed Naim Agrewala	KUMAP0105US	7206

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Joseph J. Crimaldi
Renner, Otto, Boisselle & Sklar, LLP
Keith Building, 19th Floor
1621 Euclid Avenue
Cleveland, OH 44115-2191

EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,602

Applicant(s)

Agrewala et al

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

1. Currently, claims 1-5 are pending and under consideration.

Drawings

2. This application has been filed with drawings which are acceptable for examination purposes only. The drawings are objected to for the reasons set forth on the attached form PTO-948.

Specification

3. The disclosure is objected to because of the following informalities:
 - a) page 2, line 28, "over" should be "overt",
 - b) page 6, line 9, it appears that "and" should be inserted between "tuberculosis" and "other intracellular diseases",
 - c) page 8, lines 4-5 are unclear: "The cells know to be cardinal in imparting protective immunity against intracellular infections and cancer",
 - d) throughout the specification, "leisteria" should be "listeria" and "streptococcas" should be "streptococcus",

Appropriate correction is required.

Claim Objections

4. Claim 1 is objected to because of the following informalities: 1) "leisteria" should be "listeria"; 2) "streptococcas" should be "streptococcus". Appropriate correction is required.

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Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

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The nature of the invention - process for making vaccines against tuberculosis and other intracellular pathogens.

The state of the prior art - high for preparations of various vaccines. However, vaccines against tuberculosis have been routinely unsuccessful. The history of vaccination in humans against *Mycobacterial* disease is notorious for a lack of successful protection. In addition, at the time of filing of the instant specification, there remained a lack of correlation of success in animal models with successful vaccination of humans against mycobacterial disease, as evidenced by the review article, "Evaluation of the Protective Potency of New Tuberculosis Vaccines", *Review of Infectious Diseases*, Vol. 11, Supplement 2, pages S484-S490, March-April 1989.

The amount of direction or guidance present - The specification teaches treatment of only two bacteria, *M. tuberculosis* and *S. typhimurium*, by culturing in macrophages, exposure to drugs and irradiation, with injection into mice. The specification provides no data resulting from these procedures, thus there is no evidence of actual vaccine data.

The quantity of experimentation necessary - Therefore, without any evidence of actual protection from infection or protection from disease, the instant claims directed to *M. tuberculosis* and *S. typhimurium* are merely an invitation to experiment.

In addition, there is no data for treatment or results of *M. leprae*, leishmania, other salmonella, trypanosoma, plasmodium, brucella, listeria, HIV, streptococcus, or cancer.

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8. Claims 1, 2, 3, 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite that macrophages cell lines are “selected from the group consisting of J774A, P388D1, RAW, BMC-2, THP-1, etc.;”. It is unclear what are the metes and bounds of “etc.”, i.e., what other cells lines are included.

Also, the specification teaches a cell line “J77.4” and “J774” but not J774A.

9. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recites “substantially as herein described with reference to the examples.” It is unclear: 1) what are the metes and bounds of “substantially”, and 2) which examples.

10. Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that infected cell are to be treated “with known drugs”. What is the identity and criteria for choosing such drugs?

Claim 5 recites that the preparation are treated “by the available drugs against the pathogens”. What is the criteria for determining “availability”?

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11. Claims 1, 4, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "tuberculosis and other intracellular pathogens" selected from a group comprising "cancer" and "tumor". It is unclear how cancer and tumor are "intracellular pathogens."

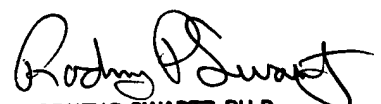
Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

December 17, 2001